

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

UNITED STATES OF AMERICA, <i>ex rel.</i>)	Civil Action No. 3:17-cv-00166-RBH
JON VITALE,)	
)	
Plaintiff,)	
)	
v.)	MIMEDX GROUP, INC.’S ANSWER
)	AND AFFIRMATIVE DEFENSES TO
MIMEDX GROUP, INC.)	THE COMPLAINT
)	
Defendant.)	
)	
)	
)	

MiMedx Group, Inc. (“MiMedx”) for its Answer and Affirmative Defenses to the Complaint filed by relator Jon Vitale (“plaintiff”) states as follows:

Response to Opening Narrative Summary

To the extent the Complaint’s opening narrative on page 1 purports to characterize the allegations in the Complaint’s numbered paragraphs, MiMedx responds by incorporating by reference its responses to the Complaint’s specific numbered paragraphs below. MiMedx denies any remaining allegations in the opening narrative on page 1.

Responses to Numbered Paragraphs

No response is required to the Complaint’s headings and subheadings. To the extent required, MiMedx denies any allegations in the headings and subheadings. Answers to all numbered paragraphs include the answer to any footnote plaintiff included in that numbered paragraph.

MiMedx answers as follows with respect to the individual numbered paragraphs of the Complaint:

JURISDICTION AND VENUE

1. This action arises under the FCA and the AKS. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 & 1345 and 31 U.S.C. §§ 3730(b) & 3732(a).

ANSWER: To the extent Paragraph 1 states legal conclusions, no response is required.

MiMedx admits that plaintiff purports to assert claims under the False Claims Act and Anti-Kickback Statute. MiMedx admits that the Court has subject matter jurisdiction over this case. MiMedx denies the remaining allegations in Paragraph 1.

2. The Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant transacts business in this District and numerous acts prohibited by federal law occurred in this District.

ANSWER: To the extent Paragraph 2 states legal conclusions, no response is required.

MiMedx admits the Court has personal jurisdiction over MiMedx and that MiMedx has transacted business in this District. MiMedx denies the remaining allegations in Paragraph 2.

3. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a).

ANSWER: Admitted.

4. Mr. Vitale's claims and this Complaint are not based upon the prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing in which the Government or its agent is a party; in a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation; or from news media, as enumerated by 31 U. S.C. § 3730(e)(4)(A). To the extent there has been a public disclosure unknown to Mr. Vitale, he is the "original source" and the public disclosure is a result of Mr. Vitale voluntarily providing this information to the United States prior to filing this *qui tam* action. See 31 U.S.C. § 3730(e)(4)(B).

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 4 and, therefore, denies those allegations.

PARTIES

5. Relator Jon Vitale is a former MiMedx sales representative with a 20-year career selling biologics and pharmaceutical products. Over the last three years, he was employed by MiMedx as a South Carolina sales representative (rep). Mr. Vitale has brought this action on behalf of the United States and its agencies, including the Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS), and the Office of Personnel Management (OPM). Mr. Vitale obtained direct personal knowledge of the facts alleged here during his employment by MiMedx.

ANSWER: MiMedx admits that plaintiff purports to bring this action on behalf of the United States and its agencies, including the Department of Health and Human Services, the Centers for Medicare and Medicaid Services (CMS), and the Office of Personnel Management (OPM). MiMedx admits that plaintiff was formerly employed by MiMedx as an account executive in South Carolina. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 5 and, therefore, denies those allegations.

6. Defendant MiMedx Group, Inc. (MiMedx) is a publically traded (NASDAQ: MDXG), for-profit company incorporated under the laws of the State of Florida with its principal place of business is 1775 West Oak Commons Court, Marietta, Georgia. MiMedx is believed to employ in excess of 170 sales representatives nationwide who sell regenerative biological products to public and private wound clinics, hospitals, and physicians' offices. MiMedx claims to be the leading distributor of amniotic tissue products used in wound, surgical, sports medicine, ophthalmic, and dental healthcare. MiMedx obtains human tissue necessary for the manufacture of its products through its wholly owned subsidiary, MiMedx Tissue Services, LLC, which located at MiMedx corporate headquarters and is a registered manufacturer of human cells, tissues, and cellular tissue-based products (HCT/Ps) operating under FDA Establishment Identifier No. 3005897621. All of the actions attributed to MiMedx in this Complaint were taken by employees and/or agents acting within the scope of their employment and/or agency with MiMedx. MiMedx was previously known by the names Surgical Biologics.

ANSWER: MiMedx admits that it is a for-profit company incorporated under the laws of the State of Florida with its principal office located at 1775 West Oak Commons Court, Marietta, Georgia. MiMedx further admits that it employs more than 170 account executives nationwide who sell MiMedx's products to customers including public and private wound clinics, hospitals,

and physicians' offices. MiMedx further admits that it develops, manufactures, and markets placental tissue-based allografts for use in the wound care, surgical, sports medicine, ophthalmic, and dental healthcare sectors, among others. MiMedx further admits that it obtains human placental tissue for use in the manufacture of its products through its wholly owned subsidiary MiMedx Tissue Services, LLC, which is located at MiMedx corporate headquarters, and is a registered processor of human cells, tissues, and cellular tissue-based products (HCT/Ps) operating under FDA Establishment Identifier No. 3005897621. MiMedx denies the remaining allegations of Paragraph 6.

STATUTORY AND REGULATORY AUTHORITY APPLICABLE TO THIS CLAIM

Federal Health Insurance Programs

7. The federal government is among the principal purchaser of MiMedx biologics products through a number of federal health insurance programs.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 7 and, therefore, denies those allegations.

8. When Congress passed the Social Security Act of 1965, it created the Medicare Program; a remedial federal health insurance program designed to ensure “adequate medical care is available to the aged throughout this country.” Hultzman v. Weinberger, 495 F.2d 1276, 1281 (3d Cir. 1974); see also Title XVIII of the Social Security Act, 42 U.S.C. §§ 426, 426A.

ANSWER: To the extent Paragraph 8 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited statutes and cases speak for themselves. MiMedx denies any remaining allegations in Paragraph 8.

9. There are four parts to Medicare: Medicare Part A (hospital insurance); Medicare Part B (medical insurance); Medicare Part C (Medicare Advantage, previously known as Medicare + Choice); and Medicare Part D (prescription drug benefit).

ANSWER: To the extent Paragraph 9 states legal conclusions, no response is required.

MiMedx denies any remaining allegations in Paragraph 9.

10. Generally, Medicare Part A pays for inpatient hospital, hospice and skilled nursing facilities for beneficiaries, as well as some home healthcare services. See 42 U.S.C. §§ 1395e-1395i-5. Prescription drugs are covered under Medicare Part A only if they are administered on an inpatient basis in a hospital and, generally, there is no patient coinsurance for drugs.

ANSWER: To the extent Paragraph 10 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited statutes speak for themselves. MiMedx denies any remaining allegations in Paragraph 10.

11. Medicare Part B covers some healthcare services and products not covered by Medicare Part A, typically outpatient care like doctor's visits and other services. Medicare Part B also pays for some types of prescription drugs and biologicals not administered in a hospital setting, but administered by a physician or other provider in an outpatient setting. See 42 U.S.C. §§ 1395k(a) & 1395x(s)(2)(A); 42 C.F.R. § 405.517.

ANSWER: To the extent Paragraph 11 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited statutes and regulations speak for themselves. MiMedx denies any remaining allegations in Paragraph 11.

12. Medicare Part C, is an optional plan, formerly called Medicare+Choice and now call Medicare Advantage plans, that combines coverage offered under Parts A & B, but is administered by a private insurance company.

ANSWER: To the extent Paragraph 12 states legal conclusions, no response is required.

MiMedx denies any remaining allegations in Paragraph 12.

13. Medicare Part D was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Pub. L. 108-173, which went into effect on January 1, 2006, subsidizes drug coverage for beneficiaries. Specifically, a “covered part D drug” means:

(A) *a drug* that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r-8(k)(2) of this title; or

(B) *a biological product* described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary), and such term includes a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

42 U.S.C. § 1395w-102 (emphasis added); see also *id.* § 1396r-8(k)(2) (defining “covered outpatient drugs” to include prescription drugs approved under the FDCA and biological products licensed under 42 U.S.C. § 262).

ANSWER: To the extent Paragraph 13 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited statutes speak for themselves. MiMedx denies any remaining allegations in Paragraph 13.

14. The Federal Employees Health Benefits Program (“FEHBP”) provides health insurance coverage for more than eight million federal employees, retirees, and their dependents. FEHBP is a collection of individual healthcare plans such as the Blue Cross and Blue Shield Service Benefit Plan (available at: <https://www.opm.gov/healthcare-insurance/healthcare/plan-information/plan-codes/2017/brochures/71-005.pdf>). FEHBP plans are managed by OPM and typically require beneficiaries to pay coinsurance for drugs and biological products comparable to a private health insurance plan.

ANSWER: To the extent the allegations of Paragraph 14 relate to the FEHBP, no further response is required because claims relating to the FEHBP were dismissed. Dkt. 78. MiMedx denies any remaining allegations in Paragraph 14.

15. While each government-funded healthcare program establishes its own reimbursement criteria, none of the aforementioned federal payors knowingly pays for healthcare products or services tainted by an unlawful inducement.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 15, and, therefore, denies those allegations.

**The Food Drug and Cosmetics Act
and the Public Health Service Act**

16. The federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 et seq., tasks the United States Food and Drug Administration (FDA) with approving new drug applications prior to their sale. See id. §§ 355 et seq.

ANSWER: To the extent Paragraph 16 states legal conclusions, no response is required. To the extent relevant to the issues in this case, the provisions of the FDCA speak for themselves. MiMedx denies any remaining allegations in Paragraph 16.

17. The FDCA defines a “drug” as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” 21 U.S.C. § 321(g)(1)(B) & (C).

ANSWER: To the extent Paragraph 17 states legal conclusions, no response is required. To the extent relevant to the issues in this case, the provisions of the FDCA speak for themselves. MiMedx denies any remaining allegations in Paragraph 17.

18. Generally, whether a product is a “drug” turns on its intended use and the nature of the claims advanced in support of its use, usually as discerned from the products label, promotional claims, advertising, and other relevant sources. See United States v. Regenerative Scis., LLC, 878 F. Supp. 2d 248, 255-56 (D.D.C. 2012) (collecting cases), aff d, 741 F.3d 1314 (D.C. Cir. 2014); see also 21 C.F.R. § 201.128 (product’s intended uses and words of similar import demonstrate intent of persons responsible for label and objective intent can be discerned through words or shown by the circumstances surrounding distribution of the article).

ANSWER: To the extent Paragraph 18 states legal conclusions, no response is required. To the extent relevant to the issues in this case, the provisions of the cited cases and regulation speak for themselves. MiMedx denies any remaining allegations in Paragraph 18.

19. Likewise, the federal Public Health Service Act (PHSA), 42 U.S.C. §§ 262 et seq., tasks FDA with regulating the licensure and marketing of biological products.¹ Id. § 262(a).

ANSWER: To the extent Paragraph 19 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the PHSA and other cited statutes speak for themselves. MiMedx denies any remaining allegations in Paragraph 19.

20. A “biologic product” is any “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product ... applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262(i)(1).

ANSWER: To the extent Paragraph 20 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited statute speak for themselves. MiMedx denies any remaining allegations in Paragraph 20.

21. In regulating biologic products under the PHSA, FDA is also authorized to make and enforce regulation necessary to prevent the intrastate introduction, transmission, and spread of communicable disease. See id. §§ 264 & 271.

ANSWER: To the extent Paragraph 21 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the PHSA speak for themselves. MiMedx denies any remaining allegations in Paragraph 21.

¹ Traditionally, FDA approves a biological product for commercial marketing by granting a license under § 262(a) after an applicant has filed a biologics license application (BLA) providing clinical data demonstrating safety and efficacy. In 2010, the Patient Protection and Affordable Care Act, Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), which established an abbreviated pathway for regulatory approval of follow-on biological products that are “highly similar” to a previously approved product (typically called a “reference product”). Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. §§ 355 et seq.).

22. In furtherance of this mandate, MIS has promulgated Part 1271 concerning the registration and treatment of human cells, tissues, and cellular and tissue-based products (HCT/Ps). 21 C.F.R. §§ 1271.1 et seq. HCT/Ps are defined as “articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.” Id. § 1271.3(d). Generally speaking, FDA has exercised its authority to regulate HCT/Ps by imposing certain registration and handling requirements. See id. §§ 1271.21—.37 & .145—.320; see also Human Cells, Tissues, and Cellular and Tissue—Based Products; Establishment Registration and Listing; Final Rule, 66 Fed. Reg. 5447 (Jan. 19, 2001) (“Registration Rule”). The Center for Biologics Evaluation and Research (CBER) is the Center within FDA that regulates biological products, including HCT/P, for human use under FDCA and PHSA.

ANSWER: To the extent Paragraph 22 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited regulations speak for themselves. MiMedx denies any remaining allegations in Paragraph 22.

23. A product can be both a drug and a biological product. See, e.g., CareToLive v. von Eschenbach, 525 F.Supp.2d 952, 957 (S.D. Ohio 2007). Except for some licensing distinctions, the FDCA applies to a biologic products licensed under the PHSA. 42 U.S.C. § 262(j); see CareToLive, 525 F.Supp.2d at 957 (“Biological products ... are generally subject to the same statutory and regulatory requirements that apply to drugs.”).

ANSWER: To the extent Paragraph 23 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited cases and statutes speak for themselves. MiMedx denies any remaining allegations in Paragraph 23.

24. At all times relevant to this action, MiMedx products fully satisfy the definition of a “drug” under the FDCA and a “biologic product” under the PHSA. Cf. Regenerative, 878 F. Supp. 2d at 256-57 (product using stem cells to promote healing in fractures, cartilage, muscle tears, and other orthopedic injuries and arthritis was a “drug”).

ANSWER: To the extent Paragraph 24 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the FDCA, PHSA, and cited case speak for themselves. MiMedx denies any remaining allegations in Paragraph 24.

The Anti-Kickback Statute

25. The federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320-7b, makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce the referral of business reimbursable under a federal health benefits program.

ANSWER: To the extent Paragraph 25 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the AKS speak for themselves.

MiMedx denies any remaining allegations in Paragraph 25.

26. “Any remuneration” means any kickback, bribe, or rebate, direct or indirect, overt or covert, cash or in kind. 42 U.S.C. § 1320a-7b(b)(1).

ANSWER: To the extent Paragraph 26 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the AKS speak for themselves.

MiMedx denies any remaining allegations in Paragraph 26.

27. AKS violations are a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both, and exclusion from federal health care programs for at least five years. See id. § 1320a-7b. In addition to the statute’s criminal penalties, the HHS Secretary has power to impose administrative penalties including exclusion and sanctions of \$10,000 per kickback violation. Id. § 1320a-7a.

ANSWER: To the extent Paragraph 27 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the AKS speak for themselves.

MiMedx denies any remaining allegations in Paragraph 27.

28. The statute’s prohibition against knowing and willful conduct in disregard of the law extends to any arrangement where *one purpose* of the remuneration is to induce referrals. United States ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 47 (D. Mass. 2011) (collecting cases).

ANSWER: To the extent Paragraph 28 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the AKS and the cited case speak for themselves. MiMedx denies any remaining allegations in Paragraph 28.

29. Generally, paying a federally insured patient's copay or coinsurance has long implicated the AKS. See OIG, Special Fraud Alert, 59 Fed. Reg. 65372 (Dec. 19, 1994) (explaining routine waiver of copays/coinsurance "results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare.").

ANSWER: To the extent Paragraph 29 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the AKS and the cited Special Fraud Alert speak for themselves. MiMedx denies any remaining allegations in Paragraph 29.

30. Such schemes increase the offeror's sales at the government's expense by inducing purchases by beneficiaries that would have been unwilling to purchase the product had they been responsible for the copay/coinsurance. Copay/coinsurance kickback schemes also taint the marketplace by diverting customers from competitors who did not offer like remuneration.

ANSWER: Denied.

31. The HHS Secretary promulgates regulations defining safe harbor practices not subject to AKS liability where the excluded practices are unlikely to result in fraud or abuse. See 42 C.F.R. §1001.952. The safe harbors set conditions that, if met, will not give rise to criminal or administrative action. No safe harbor applies to the conduct at issue here.

ANSWER: To the extent Paragraph 31 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited regulation speak for themselves. MiMedx denies any remaining allegations in Paragraph 31.

32. To the contrary, HHS's Office of Inspector General (OIG) has expressly raised concerns about conduct by donor companies to patient assistance programs (PAPs) that could implicate the AKS.

ANSWER: MiMedx admits that the HHS OIG has issued advisory bulletins addressing donations to PAPs. Those advisory bulletins speak for themselves. MiMedx denies any remaining allegations in Paragraph 32.

33. On May 21, 2014, OIG issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (Supplemental Bulletin), seeking to offer additional guidance to PAPs operated by independent charities and address risks these programs have raised since OIG's initial Special Advisory Bulletin on the issue. See OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (SAB), 70 F.R. 70623 (Nov. 22, 2005).

ANSWER: To the extent Paragraph 33 states legal conclusions, no response is required. To the extent relevant to the issues in this case, the provisions of the cited advisory bulletins speak for themselves. MiMedx denies any remaining allegations in Paragraph 33.

34. OIG's Supplemental Bulletin explains that, with respect to co-pay assistance organizations, two remuneration arrangements require scrutiny under the anti-kickback statute: "[1] donor contributions to PAPs (which can also be analyzed as indirect remuneration to patients) and [2] PAPs' grants to patients." Supp. Bulletin, 79 Fed. Reg. at 31121.

ANSWER: To the extent Paragraph 34 states legal conclusions, no response is required. To the extent relevant to the issues in this case, the provisions of the cited Supplemental Bulletin speak for themselves. MiMedx denies any remaining allegations in Paragraph 34.

35. With respect to PAP grants, OIG reiterated existing guidelines designed to ensure PAPs fulfill a charitable purpose. "We reiterate here that an Independent Charity PAP must not function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." *Id.* This means "pharmaceutical manufacturers and their affiliates should not exert any direct or indirect influence or control over the charity or its assistance program." *Id.*

ANSWER: To the extent Paragraph 35 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited Supplemental Bulletin speak for themselves. MiMedx denies any remaining allegations in Paragraph 35.

36. To ensure true charitable independence, “[b]eneficiaries should not be tied to a particular product, or to a subset of available products, to receive or continue their assistance.” Id. at 31122. OIG warned, “a disease fund that covers only a single product, or the products made or marketed by only a single manufacturer that is a major donor to the fund, will be subject to scrutiny[,]” because this conduct risks “steering patients to the drugs for which assistance is available[,] which, in turn, “increases the likelihood that the donors could use the PAPs as improper conduits to provide a subsidy to patients who use the donors’ own products.” Id. OIG is also concerned that manufacturer’s “ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support.” Id.

ANSWER: To the extent Paragraph 36 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited Supplemental Bulletin speak for themselves. MiMedx denies any remaining allegations in Paragraph 36.

37. With respect to donor conduct, OIG acknowledged that much of its guidance thus far, and many favorable advisory opinions, have focused on the conduct of independent charity PAPs, not donor companies who stand to benefit from patients receiving co-pay assistance. See id. at 31123. OIG explained that PAP conduct it has condoned thus far is based, in part, on the charity’s certification of actions that ensure independence, something it does not claim with respect to its donors. Id.

ANSWER: To the extent Paragraph 37 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited Supplemental Bulletin speak for themselves. MiMedx denies any remaining allegations in Paragraph 37.

38. By way of example, OIG has relied on PAP certification that the charity will only provide donors with aggregate data, “[t]hus, the charity would not give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those produces supported by the PAP.” Id. Describing such safeguards as “critical,” OIG warns its earlier opinions “do *not* address

actions by donors to correlate their funding of PAPs with support for their own products. Such actions may be indicative of a donor's intent to channel its financial support to copayments of its own products, which *would* implicate the anti-kickback statute." *Id.* (emphasis added).

ANSWER: To the extent Paragraph 38 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited Supplemental Bulletin speak for themselves. MiMedx denies any remaining allegations in Paragraph 38.

39. Notably, while the guidance offered by the SAB and Supplemental Bulletin expressly contemplate Medicare Part D programs, they referenced co-pay assistance programs for drugs covered under Medicare Part B as well, explaining "the principles set forth in the 2005 SAB and herein apply regardless of which Federal health care program (as defined in section 1128B(f) of the Social Security Act (the Act) covers the drugs." Supp. Bulletin 79 F.R. at 31120, n.2.

ANSWER: To the extent Paragraph 39 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited advisory bulletins speak for themselves. MiMedx denies any remaining allegations in Paragraph 39.

40. Compliance with the AKS is a material condition of payment under federal insurance programs such that violating the AKS gives rise to a false claim. See Westmoreland, 812 F. Supp. 2d at 54 (collecting cases).

ANSWER: To the extent Paragraph 40 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the cited case speak for themselves. MiMedx denies any remaining allegations in Paragraph 40.

The False Claims Act

41. The False Claims Act (FCA) provides, in relevant part, that:

any person who--(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [...]

* * *

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

ANSWER: To the extent Paragraph 41 states legal conclusions, no response is required.

To the extent relevant to the issues in this case, the provisions of the FCA speak for themselves.

MiMedx denies any remaining allegations in Paragraph 41.

FACTUAL ALLEGATIONS CONCERNING MIMEDX'S FRAUDULENT CONDUCT

42. This action concerns a deceptive scheme by MiMedx to illegally pay patient copays and coinsurance by laundering funds through a third-party charitable fund intended to assist low-income and financially distressed patients in paying their portion of the cost associated with expensive biological product treatment.

ANSWER: Denied.

43. Since at least February 2014, MiMedx has cynically correlated its contributions to PAN Foundation to the number of patients seeking to use its products while manipulating the submission of patient applications requesting foundation assistance to ensure that, once PAN Foundation began issuing grants with MiMedx contributions, MiMedx's so-called charitable gifts would only fund assistance for its own products.

ANSWER: Denied.

44. This illegal scheme has fueled profits for the company at the expense of federal health insurance programs that would not have paid for MiMedx's products had these programs known the claims arose from an elaborate fraud by the product's manufacturer.

ANSWER: Denied.

45. According to MiMedx, the total US market for its products is worth \$16 billion, while wound care, the portion of the market at issue in this case, is a \$7.7 billion industry.

ANSWER: MiMedx admits that it has previously stated that the total U.S. market for its products is worth \$16 billion and that the wound care market is a \$7.7 billion industry. MiMedx denies any remaining allegations in Paragraph 45.

46. MiMedx is a significant and growing player in this segment of the industry. For instance, as of 2015, the sale of MiMedx's products accounts for over a quarter of the biological product skin graft market. MiMedx's 2016 annual revenues exceeding \$246 million, fueled in part by a 36% growth in its wound care sales.² These numbers reflect five-plus years of exponential sales growth, growth fueled, in part, by the kickback scheme at issue here.

ANSWER: MiMedx admits that it sells products for use in the wound care sector of the healthcare market. MiMedx admits that on January 9, 2017 it issued a press release announcing that it recorded revenue for the year ended December 31, 2016 of \$246.8 million, and that its fourth quarter 2016 wound care revenue grew 36% over the fourth quarter 2015. MiMedx denies the remaining allegations in Paragraph 46.

47. This scheme violates the AKS and has resulted in the submission of kickback-tainted claims for reimbursement to federal health insurance programs actionable under the FCA.

ANSWER: Denied.

MiMedx Products

48. MiMedx develops, manufactures, and sells patented biomaterial products created using human amniotic membranes, which it claims have regenerative healing properties that can speed the healing of soft-tissue wounds.

² See MiMedx News Release, "MiMedx Fourth Quarter 2016 Revenue in Upper Range of Guidance," available at: <http://phx.comorate-ir.net/phoenix.zhtml?c=213465&p=irol-newsArticle&ID=2236369> (accessed January 16, 2017).

ANSWER: MiMedx admits that it develops, manufactures, and sells patented biomaterial products created using human membranes. MiMedx denies the remaining allegations in Paragraph 48.

49. MiMedx obtains biological materials used to manufacture its products from human placentas donated during Caesarean section births. After it is donated, this human tissue is processed using MiMedx's PURION Process, a proprietary, tissue sterilization technique. MiMedx's subsidiary, MiMedx Tissue Services, LLC, is a registered manufacturer of HCT/Ps operating under FDA Establishment Identifier No. 3005897621.

ANSWER: Admitted.

50. All of MiMedx's products, whether tissue graphs or micronized powders, are based on the premise that amniotic cells in the product include growth factors and promote cytokinesis (i.e., cell division) and angiogenesis (i.e., new blood vessel development) within soft tissue. MiMedx distinguishes its products from the competition based on patents it claims allows for the delivery of a double layer of amniotic cells (the amnion and chorion layers) to the wound site.

ANSWER: Denied.

51. While MiMedx makes a number of products, including products used in surgical and orthopedic procedures, two product lines are implicated in the scheme described here.

ANSWER: MiMedx admits that it makes products for use in surgical and orthopedic procedures. MiMedx denies any remaining allegations in Paragraph 51.

52. EpiFix is an amniotic membrane intended to aid in wound healing, specifically, the treatment of chronic and acute partial and full thickness wounds. For instance, MiMedx claims that use of this product to heal diabetic foot ulcers (DFU) shows a 92% success rate compared to just 8% success with standard of care treatment alone. EpiFix is sold in 10 sizes: 14 mm disk (GS-5140), 16 mm disk (GS-5160), 18 mm disk (GS-5180), 2 cm x 2 cm (GS-5220), 2 cm x 3 cm (GS-5230), 2 cm x 4 cm (GS-5240), 3cm x 4 cm (GS-5340), 4 cm x 4 cm (GS-5440), 5 cm x 6 cm (GS-5560), and 7 cm x 7 cm (GS-5770). EpiFix is also sold in a "mesh configuration," which is essentially the same product sold in three sizes: 2 cm x 3 cm (ES-2300), 3.5 cm x 3.5 cm (ES-3300), and 4 cm x 4.5 cm (ES-4400).

ANSWER: MiMedx denies that EpiFix is sold in only 10 sizes. MiMedx denies that EpiFix in a “mesh configuration” is sold in only three sizes. MiMedx otherwise admits the remaining allegations in Paragraph 52.

53. EpiFix Micronized is an amniotic powder intended to aid chronic and acute partial and full thickness wound healing and for use intradermal injections. Epi Micronized is sold in 40 mg (EI-5050), 100 mg (EI-5125), and 160 mg (EI-5200) sizes.

ANSWER: Admitted.

Diabetic Foot Ulcers (DFU) and Venous Leg Ulcers (VLU)

54. While MiMedx claims its products are efficacious to treat a broad range of wounds, from surgical to dental and everything in between, two disease states that cause difficult to heal wounds are of primarily at issue here.

ANSWER: MiMedx admits that its products have been shown to be efficacious to treat a variety of wounds. MiMedx denies any remaining allegations in Paragraph 54.

55. Diabetic foot ulcers (DFU) are open sores or wounds, commonly located on the bottom of the foot, caused by neuropathy, poor circulation, foot deformity, friction or pressure, trauma, and long-term elevated blood glucose. Diabetic Wound Care, American Podiatric Medical Association website, <http://www.apma.org/Learn/FootHealth.cfm?ItemNumber=981> (accessed Jan. 14, 2017). DFUs are often difficult to heal because elevated blood glucose diminishes the body’s natural ability to fight infection.

ANSWER: To the extent relevant to the issues in this case, the provisions of the cited website speak for themselves. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 55 and, therefore, denies the allegations contained therein.

56. An inability to heal a DFU can have serious consequences, including amputation and increased morbidity. Approximately 15 percent of patients with diabetes will develop a DFU during their lifetime and six (6) percent will be hospitalized due to infection or other ulcer-related

complication. Id. Approximately 14-24 percent of diabetic patients with a DFU require an amputation and foot ulceration precedes 85 percent of diabetes-related amputations. Id.

ANSWER: To the extent relevant to the issues in this case, the provisions of the cited website speak for themselves. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 56 and, therefore, denies the allegations contained therein.

57. A venous leg ulcer (VLU), also called a stasis ulcer, is an ulcer caused by static blood flow in the leg, usually caused by some abnormality, blockage, or failure of leg veins. Venus Diseases: Types, Cleveland Clinic website, <http://my.clevelandclinic.org/health/articles/arterial-vascular-disease/types-venous-disease> (accessed Jan. 14, 2017). VLUs are located below the knee and typically found on the inner part of the leg above the ankle. Id. Like DFUs, VLU are difficult to heal and frequently return. See id.

ANSWER: To the extent relevant to the issues in this case, the provisions of the cited website speak for themselves. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 57 and, therefore, denies the allegations contained therein.

MiMedx Sales Practices

58. In January 2014, Mr. Vitale joined MiMedx as a sales representative (rep) responsible for the company's South Carolina territory. As the company's customer base grew, he ceded territory to other reps. When he left the company in December 2017, his territory comprised a geographic area stretching from Seneca, South Carolina, through Columbia, to Sumter, South Carolina. This territory included counties in South Carolina's Upstate and Midlands regions.

ANSWER: MiMedx admits that plaintiff was hired by MiMedx in January 2014 as an account executive in South Carolina, and that plaintiff's employment with MiMedx was terminated in December 2016. MiMedx denies any remaining allegations in Paragraph 58.

59. MiMedx “customers” are hospitals, wound care centers, and private physician offices. Generally, speaking these customers fall into two categories: “federal” and non-federal or “commercial” accounts.

ANSWER: MiMedx admits that its customers include hospitals, wound care centers, and physician offices and that it has referred at times to customers as being “federal” or “commercial.” MiMedx denies any remaining allegations in Paragraph 59.

60. MiMedx federal accounts primarily consist of hospitals owned and operated by the Department of Veterans Affairs (VA) and the Department of Defense (DoD). Generally speaking, there are few reimbursement restrictions³ on product use and these accounts are serviced through the Federal Supply Schedule (FSS) program. Mr. Vitale serviced three federal accounts in his territory, include the Dorn Veterans Administration Hospital in Columbia. These federal accounts are not at issue in this action.

ANSWER: MiMedx admits that its customers include facilities operated by the VA and DoD. MiMedx further admits that plaintiff called on the Dorn Veterans Administration Hospital in Columbia, South Carolina while he was employed by MiMedx. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 60 and, therefore, denies those allegations.

61. During the time relevant to this action, Mr. Vitale serviced approximately 15 commercial accounts, primarily wound care centers and private physician offices, including:

- a. Abbeville Area Medical Center (Abbeville, SC);
- b. Columbia Foot Clinic (Columbia, SC);
- c. Elgin Podiatry (Columbia, SC);
- d. The Foot Institute (Columbia, SC);

³ Unlike commercial accounts that reimbursed MiMedx products based on the square cm and subjected doctors and patients to certain reimbursement guidelines, federal accounts had no patient guidelines, meaning physicians were able to use as many products without any limitation on reimbursement. In June 2016, Dorn enacted patient guidelines designed to curb this practice.

- e. Moore Orthopedics, now Palmetto Health Orthopedics (Columbia, SC);
- f. Midlands Orthopedics (Columbia, SC);
- g. Oconee Medical Center (Seneca, SC);
- h. Palmetto Health Advanced Wound Care (West Columbia, SC);
- i. Piedmont Podiatry Associates (Greenville, SC);
- j. Providence Hospital (Columbia, SC);
- k. Toumey Wound Care Center, now Palmetto Health (Sumter, SC); and
- l. Upstate Podiatry (Simpsonville, SC).

With the exception of Elgin Podiatry and (perhaps) The Foot Institute, all of the foregoing commercial customers treated patients with MiMedx products whose sale was tainted by the kickback scheme at issue here.

ANSWER: Denied.

62. Prior to calling on customers, Mr. Vitale received general instruction in biology and specific instruction concerning MiMedx products, the theory behind the products, and the alleged benefits of their use, particularly with respect to their purported benefits over competitors.

ANSWER: To the extent the allegations in Paragraph 62 are based upon plaintiff's recollection of instruction he allegedly received, MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 62, and, therefore, denies those allegations. MiMedx denies any remaining allegations in Paragraph 62.

63. Mr. Vitale also received instruction concerning scientific literature and clinical studies that purportedly support MiMedx's claims. Mr. Vitale was also trained on specific sales tactics designed to increase sales. This training included the use of PAPs, specifically PAN Foundation, as a resource to complete sales where patients who would otherwise be unable to afford MiMedx products due to patient responsibility costs—i.e., copays and coinsurance.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 63, and, therefore, denies those allegations.

64. MiMedx sales strategy to commercial customers was designed to get reps into physician offices in a “consulting” capacity that allowed direct interaction with patients, clinic staff responsible for treating patients, and billing staff tasked with processing paperwork to obtain payment. This incremental, relationship-building strategy not only allowed reps to become advocates for their products’ use, but, as explained below, granted access to protected patient healthcare records essential to the kickback scheme at issue here.

ANSWER: Denied.

65. First, Mr. Vitale and other reps were trained to create a relationship with customers by bringing free lunches to the office and taking physicians and nurses to dinner.

ANSWER: Denied.

66. While physician interaction was always important, the true target of this influence campaign in wound care centers was the potential customer’s program director who could aid in getting a product approved for use by the customer’s office or clinic. Alternatively, in a private physician’s offices, a physician typically decided which products to approve.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 66 and, therefore, denies those allegations.

67. MiMedx reps argued to program directors and private physicians that the use of its products—far more expensive than most wound care products—would generate profits for the customer, which charge for the sale and application (i.e., grafting) of MiMedx products at a higher rate than for the use of standard of care products. As an individual tasked with clinical and fiscal responsibilities, program directors were often far more receptive to these arguments than physicians, particularly when the program director was employed by a private management company (e.g., Healogics, Inc.).

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 67 and, therefore, denies those allegations.

68. MiMedx reps also used speaker programs to reward customer physicians and solicit new customers. The company’s speaker programs paid customer physicians between \$600 and

\$5,000 per “speech,” to read Power Point slide decks prepared by MiMedx extoling the benefits of the company’s products to fellow physicians.

ANSWER: Denied.

69. This influence campaign was designed to get potential customers to approve the use of MiMedx products in their facility and then expand the use of those products to new patients, uses, and product lines.

ANSWER: Denied.

70. To facilitate timely use and availability of MiMedx products, products were typically ordered and distributed to customers on consignment or through direct purchase with a par order agreement.

ANSWER: MiMedx admits that customers order MiMedx products on consignment and through direct purchase. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 70 and, therefore, denies those allegations.

71. Until early 2016, MiMedx sought to incentivize customers to adopt this consignment relationship by holding customer purchase orders (POs) until the end of the month to allow the client to receive reimbursement from the patient’s insurer before paying MiMedx.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 71 and, therefore, denies those allegations.

72. While this incentive program was never memorialized in writing, it was taught to all MiMedx reps at a national sales rep meetings by John Moore, an award-winning MiMedx rep who later become a company sales manager.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 72 and, therefore, denies those allegations.

73. Once a customer approved the products for use, reps gave customers a Clinical Resource Book. A Clinical Resource Book is comprised of six main tabs, titled:

- a. Tissue Log—used to document the use of a product in the clinic by recording a patient identifier, date, product bar code, size, graft application number, and the physician or nurse who participated in the procedure;
- b. Insurance Verification Request (IVR) and Skin Substitute Checklist (also called a “face sheet”)—forms used to obtain prior insurance authorization from insurers (discussed in detail below);
- c. Insurance Verification SENT—to file completed IVR forms;
- d. Consignment Order Request Forms—used to place orders for additional products;
- e. Consignment Billing/Feedback Form—used for billing;
- f. Consignment Billing SENT—to file completed billing forms;
- g. Purchase Request—used to make a direct purchase order; and
- h. Payer Coverage—providing coverage guidance for particular payors and specific product and procedure billing codes to facilitate reimbursement of MiMedx products.

ANSWER: MiMedx admits that some account executives provided customers a Clinical Resource Book. MiMedx denies any remaining allegations in Paragraph 73.

74. After establishing a Clinical Resource Binder in a customer’s facility, reps asked nurses or administrators to obtain physician signatures on blank insurance verification forms that would enable clinic staff, or MiMedx reps, to submit preapproval papers to patient insurers.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 74 and, therefore, denies those allegations.

75. Once a customer approved use of MiMedx products in its facility, Mr. Vitale, and other effective reps, were taught to “leverage” their relationship in an effort to achieve status as a “consultant” capable of helping customers identify patients who could benefit from use of the products and new uses for the products.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 75 and, therefore, denies those allegations.

76. MiMedx instructed its reps, all of whom were paid on commission as a percentage of sales, to earn “clinic time” with clients. Clinic time, they were told, resulted in new patient identification.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 76 and, therefore, denies those allegations.

77. Initially, reps would request clinic time for educational purposes. Once inside a clinic, reps, including Mr. Vitale, would look to help with menial tasks to further ingratiate themselves to clinic staff and create an appearance that sales reps were part of the customer’s healthcare team. For example, Mr. Vitale would often wipe down examination tables in between patients or retrieve patient charts from the file room to “save time” for doctors and nurses.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 77 and, therefore, denies those allegations.

78. MiMedx specifically taught reps that retrieving patient charts from and for clinic staff was an effective way to obtain patient information and identify new product targets and reps were coached on techniques that would result in granting them access to this federally protected patient information.

ANSWER: Denied.

79. Once a rep identified a possible patient/sales target, Mr. Vitale and others were instructed to offer to come back at a later date to “follow-up” and check on the patient’s medical outcome. This sales strategy created an appearance with physicians and nurses of a shared interest in patient wellbeing while securing additional “clinic time” at some future date, which created an opportunity to “probe” for other potential patients. This strategy was taught to Mr. Vitale during his January 2014 new hire training and routinely reinforced during subsequent company trainings.

ANSWER: To the extent the allegations in Paragraph 79 are based upon plaintiff’s recollection of instruction he allegedly received, MiMedx lacks information sufficient to form a

conclusion as to the truth or falsity of those allegations and, therefore, denies those allegations.

MiMedx denies any remaining allegations in Paragraph 79.

80. This strategy also enabled reps to identify patients whose insurers would not presently reimburse for the use of MiMedx products, but for whom they *would* pay at some future date if the wound failed to heal.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 80 and, therefore, denies those allegations.

81. Specifically, Mr. Vitale and other reps targeted DFU and VLU patients with this strategy because insurers, including federal payors, typically condition reimbursement for advanced therapies such as the use of MiMedx's products with a documented failure to heal.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 81 and, therefore, denies those allegations.

82. Medicare guidelines will not reimburse the cost of advanced VLU therapy unless a wound fails to close within four weeks or show 50% improvement.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 82 and, therefore, denies those allegations.

83. Likewise, DFUs must persist for four weeks and show less than 50% improvement before an afflicted patient qualifies for advanced therapy.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 83 and, therefore, denies those allegations.

84. MiMedx reps were trained to preach "speed to closure," which highlighted the difficulty in healing DFUs and VLUs and argued that faster healing in these vulnerable populations reduced the risk of infection, amputation, and, eventually, death.

ANSWER: Admitted.

85. But since insurers would not reimburse the use of MiMedx products prior to four weeks, reps were able to identify possible candidates for their products during the pre-four-week period, persuade physicians and nurses to order the product's use, and obtain pre-approval from the patient's insurer.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations regarding whether unnamed "insurers" would "reimburse the use of MiMedx products prior to four weeks" and, therefore, denies those allegations. MiMedx denies any remaining allegations in Paragraph 85.

86. Other reimbursement strategies employed by Mr. Vitale and other MiMedx reps include advocating for pressure wounds to be redefined as DFUs after four weeks to facilitate approval. Likewise, trauma wounds would typically not be covered unless, after four weeks, physicians attributed its failure to close and heal to a venous insufficiency or diabetes.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations regarding strategies allegedly employed by plaintiff and other unnamed "MiMedx reps," and, therefore, denies those allegations. MiMedx also lacks information sufficient to form a conclusion as to the truth or falsity of the allegations regarding the circumstances in which "trauma wounds would typically . . . be covered," and, therefore, denies those allegations. MiMedx denies any remaining allegations in Paragraph 86.

87. Another sales technique Mr. Vitale and his colleagues used to develop this consultant status was to ask nurses or clinic managers to schedule reps for a "wound care clinic" day that granted reps access to physicians and patients for the express purpose of reviewing patient cases and files in the hopes of identifying new patients that could use MiMedx products.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations regarding techniques allegedly employed by plaintiff and his unnamed

“colleagues” and, therefore, denies those allegations. MiMedx denies any remaining allegations in Paragraph 87.

88. This strategy might also entail convincing clinic staff to schedule a wound care clinic focused on a MiMedx product well-established with that customer, such as EpiFix, but then using that patient access to recommend or “advise” that physicians and nurses try other MiMedx products. Notably, Mr. Vitale and other reps frequently had direct patient interaction during these sales manufactured sales opportunities.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations regarding strategies allegedly employed by plaintiff and other unnamed “reps” and, therefore, denies those allegations. MiMedx denies any remaining allegations in Paragraph 88.

89. In a similar approach, reps frequently identified patient cases that might be eligible for MiMedx products and asked nurses to let them (the rep) know when the procedure would be scheduled so the rep could attend or schedule corresponding clinic time.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations regarding the approach allegedly employed by unnamed “reps” and, therefore, denies those allegations. MiMedx denies any remaining allegations in Paragraph 89.

90. These sales techniques were reinforced during annual, five-day national sales meetings in which company reps sat through seminars purporting to instruct on new clinical data, while encouraging them to “think outside the box” to complete sales, highlighting examples of successful reps and rep techniques.

ANSWER: MiMedx admits that it held annual national sales meetings, that at some meetings information was provided on new clinical data, and that examples of successful sales techniques were discussed. MiMedx lacks information sufficient to form a conclusion as to the

truth or falsity of the remaining allegations in Paragraph 90 and, therefore, denies those allegations.

91. For example, one such technique taught reps to prompt physicians to identify new possible applications and patient universes for MiMedx sales through the use of hypothetical questions like, “Do you have any patients who...” followed by reference to a specific condition or application being targeted for new use.

ANSWER: Admitted.

92. These techniques were effective. For example, in 2014, his first year as a MiMedx rep, Mr. Vitale sold \$1.9 million worth of MiMedx products.

ANSWER: MiMedx admits that in 2014, plaintiff sold \$1,957,095 worth of MiMedx products. MiMedx denies any remaining allegations in Paragraph 92.

93. MiMedx sale’s philosophy behind these strategies was simple. Reps were told clinic time led to the submission of Insurance Verification Requests (IVRs). A certain percentage of IVRs would result in approval that, in turn, resulted in sales.

ANSWER: MiMedx admits that clinic time could lead to the submission of IVRs, and that IVRs may result in approval that could result in sales. MiMedx denies any remaining allegations in Paragraph 93.

94. Thus, much of the thrust behind MiMedx sales strategy was to facilitate the submission of IVRs. For instance, in February 2016, the company set a goal of 30 IVRs per week.

ANSWER: Denied.

95. In order to ensure paperwork for its products was timely processed, MiMedx trained reps to take on administrative tasks handling protected patient information.

ANSWER: Denied.

96. Clinic staff—nurses, clinic managers, and billing staff employed by the clinic—are responsible for seeking pre-approval from patients’ insurers, including federal payors. Typically, this entails submitting some form of insurance verification form with patient insurance, demographic, and healthcare information along with any charts or other healthcare records required by the evaluating insurer.

ANSWER: MiMedx admits that insurance verification sometimes involves submission of insurance, demographic, and healthcare information. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 96 and, therefore, denies those allegations.

97. When seeking pre-approval for MiMedx products, customers were encouraged to use, and did use, the IVR and attached Skin Substitute Checklist, typically also called a “face sheet,” contained in the Clinic Resource Book to convey this information to insurers. These forms required the disclosure of sensitive patient information including:

- a. Name, address, date of birth, Social Security number (SSN), and contact information;
- b. Insurance information, primary and secondary payors;
- c. Medical history;
- d. Diagnostic information; and
- e. Physician and procedure information, among other details.

Recently, MiMedx customers have also been attaching the last three physician notes from the patient’s chart to support the IVR submission to insurers.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 97 and, therefore, denies those allegations.

98. MiMedx IVR forms include at the top of the form the reps name and a MiMedx fax number insurers are asked to use to fax approvals. Pre-approval typically takes 48 hours.

ANSWER: MiMedx admits that the IVR form includes a place for the account executive's name and a MiMedx fax number. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 97 and, therefore, denies those allegations.

99. When an insurer, including federal payors, grant pre-approval, the approval is faxed to MiMedx where it is received by a reimbursement specialist. Reimbursement specialists prepare detailed patient reports for reps that alert the rep to the approval and identify each patient's primary and secondary (if any) insurer.

ANSWER: Denied.

100. Pre-approval is a critical component of MiMedx's sales strategy because, unlike hospital, which do not require pre-approval, Medicare guidelines require wound centers, surgery centers, and private offices to obtain pre-approval.

ANSWER: Denied.

101. To ensure clinic staff submits IVRs in a timely manner, reps frequently follow up with nurses and billing staff to ensure IVRs for patients identified as possible sales opportunities have been timely submitted. Reps used a method called an "A&P" calendar to track actual and potential patients for follow up via future telephone calls or clinic visits.

ANSWER: MiMedx admits that account executives may use an "Actual and Potential" calendar to track actual and potential patients. MiMedx denies any remaining allegations in Paragraph 101.

102. MiMedx also encourages reps to submit them for staff, which relieves clinic billing staff of an administrative task and places it in the hands of individuals (reps) with a pecuniary incentive to ensure it happens.

ANSWER: Denied.

103. As a further incentive to customers, MiMedx also guaranteed its customers' claims for reimbursement through a Service Guarantee Program. Under the guarantee program, MiMedx offered customers the services of company reimbursement specialists in coding a claim and submitting any necessary appeals. MiMedx promised customers that if they used the company's reimbursement specialists, who were trained certified coders, to submit claims and pursue insurance appeals, then MiMedx would waive payment on any claim rejected by an insurer.

ANSWER: Denied.

**Patient Access Network (PAN) Foundation's
Co-pay Assistance Program**

104. Patient Access Network (PAN) Foundation is a § 501(c)(3) corporation that provides "patient assistance" in the form of grants to aid patients suffering from certain life-threatening, chronic, and rare diseases who have insurance, but cannot afford the costs associated with coverage. Specifically, PAN Foundation grants fund the cost of deductibles and patient copays and coinsurance—costs that can be prohibitive to financially distressed patients seeking to use expensive drugs to treat diseases such as various cancers, cystic fibrosis, multiple sclerosis, rheumatoid arthritis, and others.

ANSWER: MiMedx admits that the PAN Foundation is a § 501(c)(3) corporation that provides charitable grants to patients. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 104 and, therefore, denies those allegations.

105. For example, Medicare Part B currently requires patients to pay \$183 annual deductible, after which patients are responsible for 20% of the Medicare-approved amount for most doctor services, outpatient therapy, and durable medical equipment.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 105 and, therefore, denies those allegations.

106. Medicare Part D requires patients to pay either a co-pay⁴ or co-insurances⁵ based on a tiered drug schedule. Additionally, most Medicare Part D plans have a coverage gap (also

⁴ A co-pay is a set amount (e.g., \$10 per prescription).

⁵ Coinsurance requires a patient to pay a percentage (e.g., 25%) of the overall drug cost.

called the “donut hole”) that limits what the drug plan will cover for drugs. For example, the 2017 donut hole for Part D beneficiaries begins after beneficiaries have spent \$3,700 on covered drugs.⁶

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 106 and, therefore, denies those allegations.

107. Patient Assistance Programs (PAPs), like PAN Foundation, offer patients assistance in meeting these costs when deductibles, co-pays, and the coverage gap would otherwise be prohibitive to these patients receiving treatment.

ANSWER: Admitted.

108. To qualify for PAN Foundation assistance, patients must be (1) receiving treatment of disease for which there is an assistance program fund, (2) have health insurance that covers the medication for which the patient seeks assistance, (3) the medication sought after directly treats the disease, (4) the patient’s income falls at or below 400 or 500% (depending on the fund) of the federal poverty level, and (5) the patient resides and receives treatment in the United States.⁷

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations based on the referenced website and, therefore, denies those allegations.

109. PAN Foundation grants are issued from one of a number of “disease funds” that target specific disease states. These disease funds are funded by “charitable” contributions by drug and biologic product manufacturers, like MiMedx, that stand to gain from ensuring that patients that cannot afford the co-pays and coinsurance associated with the use of their products receive funding assistance.

ANSWER: MiMedx admits that the PAN Foundation maintains a number of disease funds that provide grants to patients with specific disease states. MiMedx admits that it has made charitable contributions to the PAN Foundation. MiMedx lacks information sufficient to form a

⁶ See “Costs in the coverage gap,” Medicare website, <https://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html> (accessed Jan. 16, 2017).

⁷ See PAN Foundation website, <https://www.panfoundation.org/index.php/en/patients/assistance-programs> (accessed Jan. 16, 2017).

conclusion as to the truth or falsity of the allegations relating to the sources of funding for all of those disease funds and, therefore, denies those allegations. MiMedx denies any remaining allegations in Paragraph 109.

110. For instance, PAN Foundation presently operates a DFU fund and a VLU fund that each award up to \$3,500 per patient annually.⁸ Prior to December 2015, grants to patients with these disease states were issued from a single fund, however, as described below, the program operated the same before and after the funds were split.

ANSWER: MiMedx admits that PAN presently operates a DFU fund and a VLU fund, and that at some point in the past grants for both disease states were issued from a single fund. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 110 and, therefore, denies those allegations.

111. Applicants seeking support from these funds (or others) can apply online (<https://www.panapply.org/>) or call 1-866-316-7263. Patients seeking assistance must submit an application demonstrating financial need.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 111 and, therefore, denies those allegations.

112. PAN Foundation grants are awarded on a first-come, first-serve basis until grant funding is exhausted. Applicants are notified on the PAN Foundation website as to whether a particular disease state's fund is funded and thus "open" to receive applications.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 112 and, therefore, denies those allegations.

⁸ See PAN Foundation website, <https://www.panfoundation.org/index.php/en/patients/assistance-programs/diabetic-foot-ulcers> & <https://www.panfoundation.org/index.php/en/patients/assistance-programs/venous-leg-ulcers> (accessed Jan. 16, 2017).

113. Grants are typically paid directly by the foundation to physicians, providers, and suppliers, however, patients can also receive grant funds directly if for reimbursement.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 113 and, therefore, denies those allegations.

114. Beginning with its 2005 SAB, and continuing through a series of advisory opinions a specific to PAN Foundation and up to its 2015 Supplemental Bulletin, OIG has cautiously condoned copay/coinsurance assistance foundations to operate without implicating the AKS, conditioned upon the existence of certain characteristics designed to ensure separation between the funds and their industry donors.

ANSWER: To the extent Paragraph 114 states legal conclusions, no response is required. To the extent relevant to the issues in this case, the provisions of the referenced advisory opinions speak for themselves. MiMedx denies any remaining allegations in Paragraph 114.

**MiMedx Manipulates Patient Applications and “Charitable”
Donations to Ensure Contributions Only Fund MiMedx Products**

115. For almost three years, MiMedx has heavily promoted PAN Foundation’s patient assistance program for DFU and VLU funding assistance while manipulating the patient application process to ensure the entirety of its so-called charitable donations fund patients seeking use of MiMedx products.

ANSWER: Denied.

116. Since he was hired in January 2014, all MiMedx training and training materials have instructed Mr. Vitale and other reps to promote patient use of PAN Foundation assistance.

ANSWER: Denied.

117. During his initial training, Mr. Vitale was instructed to promote PAN Foundation as a funding resource for patients.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 117 and, therefore, denies those allegations.

118. Training materials also reinforced this instruction. For example, MiMedx’s training brochure, called “BASE Guide: Blueprint for Achieving Sales Excellence,” the company offers reps a step-by-step guide to its sales strategy for commercial sales, emphasizing many of the strategies discussed above. One such slide includes a step-by-step graphic. Step one entails submitting an IVR, while steps two and three require reps to identify PAN eligibility and obtain PAN approval. The BASE Guide also instructs reps to “Always confirm PAN is open and available for funding claims.”

ANSWER: MiMedx admits that it has had a training document called “BASE Guide: Blueprint for Achieving Sales Excellence” (“BASE Guide”). MiMedx admits that a version of the BASE Guide includes a slide that states, “IVR Submitted,” “Patient Approved/PAN Eligible,” and “Patient Approved/PAN Approved.” MiMedx admits that a version of the BASE Guide includes a slide that states, “Always confirm PAN is open and available for funding claims.” MiMedx denies any remaining allegations in Paragraph 118.

119. Prior to February 2014, the company urged reps to submit PAN Foundation claims quickly in the hope that MiMedx products would be among those for which the DFU and VLU funds help pay for before the funds were exhausted. During this period, Mr. Vitale received once such communication from management emphasizing that a failure to act quickly could result in the fund being exhausted by grants issued to pay for competitor products.

ANSWER: MiMedx admits that it encouraged representatives to help enable qualifying patients in need of financial assistance to take advantage of the availability of PAN funds. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 119 and, therefore, denies those allegations.

120. By February 2014, MiMedx, which contributed to a PAN Foundations DFU and VLU fund, grew tired of its purportedly charitable gifts funding, and thus enabling, competitor sales and sought to make a change.

ANSWER: Denied.

121. This change was announced in a February 2014 email from Senior Director of Sales Operations, Lou Roselli, who wrote to the MiMedx sales force explaining MiMedx would be funding the PAN Foundation fund and would alert reps of when the fund opens and closes so reps could begin collecting patient names.

ANSWER: To the extent the allegations of Paragraph 121 are based upon or purport to characterize documents, MiMedx states that such documents are the best evidence of their contents. MiMedx denies any remaining allegations in Paragraph 121.

122. In an email send in late February 2014, Roselli told reps that MiMedx would be funding PAN Foundation in the near future, would inform reps when the fund opened, and that they should begin collecting the names of possible patient applicants. In other words, whereas reps were previously instructed to submit PAN Foundation names as quickly as possible, beginning in February 2014, MiMedx would coordinate its contributions to the funds with reps' submission of patient applications.

ANSWER: To the extent the allegations of Paragraph 122 are based upon or purport to characterize documents, MiMedx states that such documents are the best evidence of their contents. MiMedx denies any remaining allegations in Paragraph 122.

123. Around this same time frame, PAN Foundation agreed to cover patient coinsurance under Medicare Part B with grants from its DFU and VLU fund. In a February 18, 2014 email to MiMedx sale reps, Roselli reported the development while suggesting MiMedx had inside information concerning DFU funding levels:

I just heard back from PAN and they will be able to cover the full patient responsibility in the hospital outpatient setting. If you run into an issues [sic] please let me know and I can help communicate with PAN to solve and [sic] bumps in the road as this is a new policy for PAN.

There are limited DFU funds left so get them while they last.

We will keep you posted on our ability to reopen the VLU fund.

See Email L. Roselli to Sales (attached as **Exhibit A**).

ANSWER: MiMedx admits that Paragraph 123 quotes a portion of the document attached as Exhibit A. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 123 and, therefore, denies those allegations.

124. At all times relevant to this action, Roselli is the MiMedx manager responsible for the company's contact with PAN Foundation and for coordinating the company's contributions to foundation funds.

ANSWER: Denied.

125. On February 28, 2014, Mr. Vitale's supervisor, Regional Sales Director Shawn DeFord, sought to reinforce use of the PAN Foundation program by his reps in an email stating, "Please utilize this program to get more patients covered." Email from S. DeFord to Atlantic Coast Region (attached as **Exhibit B**).

ANSWER: MiMedx admits that Paragraph 125 quotes a portion of the document attached as Exhibit B, and that Shawn DeFord was plaintiff's supervisor. MiMedx denies the remaining allegations in Paragraph 125.

126. By April 2014, it was clear MiMedx sought to coordinate its contributions to PAN Foundation, which would result in "opening" the fund to application, with the bulk submission of patient applications held by reps waiting for the fund to open, the total sum of which matched the dollars contributed.

ANSWER: Denied.

127. In an April 14, 2014 email to Mr. Vitale and other reps concerning the company's second quarter (Q2) forecast, Regional Sales Director Kirk Erickson asked his reps for feedback concerning what sort of profits they could expect if patients were covered at 100 percent. Mr. Vitale believes this was an effort by management to discern whether, and on what terms, MiMedx would continue funding PAN Foundation.

ANSWER: To the extent the allegations in Paragraph 127 are based upon what plaintiff believes, MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of

those allegations and, therefore, denies those allegations. To the extent the allegations of Paragraph 127 are based upon or purport to characterize documents, MiMedx states that such documents are the best evidence of their contents. MiMedx denies the remaining allegations in Paragraph 127.

128. By this time, reps were receiving email notice from MiMedx's corporate headquarters alerting them when PAN Foundation's fund would open. Initially, these alerts gave reps 24-hours' notice followed by an alert the fund was open. More recently, reps receive three notices: an email approximately four days out, a 24-hour notice, and notice when the fund opened.

ANSWER: To the extent the allegations of Paragraph 128 are based upon or purport to characterize documents, MiMedx states that such documents are the best evidence of their contents. MiMedx admits that, at times, account executives received emails notifying them when MiMedx became aware that a PAN Foundation fund would open. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 128 and, therefore, denies those allegations.

129. Sometimes, Mr. Vitale received notice the fund would open via text message. For instance, DeFord, recently texted Mr. Vitale, "We are anticipating that the PAN DFU and VLU fund will open on Wednesday, January 4th 2017 at around 12:00 EST. I will send out an email when it is confirmed to be open."

ANSWER: To the extent the allegations of Paragraph 129 are based upon or purport to characterize documents, MiMedx states that such documents are the best evidence of their contents. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 129 and, therefore, denies those allegations.

130. On or around December 2015, PAN Foundation split its fund into two separate funds: one for DFUs and another of VLUs. Rosselli alerted sales reps to this change in a series of December 11, 2015 emails, first explaining "[t]he PAN fund will be open on Monday, December

1th [sic] at 12 pm to accommodate both the East and West Coast. Please ensure your customers are prepared to register patients in need as the fund tends to close quickly within 1–2 days.” Email L. Roselli to L. Clark (attached as **Exhibit C**). In a second email (sent not one minute later), he added, “[a]lso the fund is not [sic] dived [sic] into 2 funds: Diabetic Foot Ulcer and Venous Leg Ulcer. Ensure patients are registered into the correct fund.” Email L. Roselli to L. Clark (attached as **Exhibit D**).

ANSWER: MiMedx admits that PAN formed a VLU fund in or around 2015, and that Paragraph 130 quotes portions of the documents attached as Exhibits C and D. MiMedx denies the remaining allegations in Paragraph 130.

131. Logistically, the scheme requires reps to prepare patient applications and hold them until they receive notice the fund is opening.

ANSWER: Denied.

132. This process begins once an IVR is submitted to a MiMedx reimbursement specialist, a company employee tasked with verifying patient insurance benefits (along with any secondary coverage) and confirming copay/coinsurance details.

ANSWER: MiMedx admits that MiMedx reimbursement specialists are MiMedx employees tasked with verifying patient insurance benefits. MiMedx denies the remaining allegations in Paragraph 132.

133. For example, if the patient is insured by Medicare, the reimbursement specialist contacts the fiscal intermediary charged with administering the beneficiary’s plan and claims she is calling on behalf of the client (i.e., the clinic) in an effort to verify patient benefits.

ANSWER: MiMedx admits that MiMedx reimbursement specialists interact with patients’ insurers in an effort to verify patient benefits. MiMedx denies the remaining allegations in Paragraph 133.

134. Once the reimbursement specialist compiles a patient’s insurance information, she faxes a verification of benefits to the client.

ANSWER: MiMedx admits that MiMedx reimbursement specialists may fax a verification of benefits to the client after verifying a patient's insurance information. MiMedx denies the remaining allegations in Paragraph 134.

135. MiMedx sales reps obtain the verification either from the clinic or as part of a nightly report sent from the reimbursement specialist. Reps also receive weekly reports from reimbursement specialist detailing the insurance information for all potential patient customers.

ANSWER: MiMedx admits that MiMedx account executives could receive verification from a customer or reports from MiMedx reimbursement specialists. MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the remaining allegations in Paragraph 135 and, therefore, denies those allegations.

136. Mr. Vitale and other reps were trained to use these patient insurance reports to target patients who did not have 100 percent insurance coverage, and therefore would be required to pay a copay or coinsurance, for PAN Foundation assistance.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 136 and, therefore, denies those allegations.

137. Depending on the client, reps would contact the office, contact the patient, or have the client contact the rep so the rep could obtain the number of people in the patient's household, household income, and whether they file tax returns. With this information in hand, the rep had everything necessary to submit the patient's PAN Foundation application.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 137 and, therefore, denies those allegations.

138. Instead of submitting applications immediately, Mr. Vitale and his colleagues held this patient information until they received notice from MiMedx the fund would open.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 138 and, therefore, denies those allegations.

139. These notices come via mass email to the MiMedx sales reps, with reps now receiving notice 94 and 24 hours prior to the fund opening, as well as notice that the fund is open.

ANSWER: To the extent the allegations of Paragraph 139 are based upon or purport to characterize documents, MiMedx states that such documents are the best evidence of their contents. MiMedx admits that, at times, account executives received emails notifying them when MiMedx became aware that a PAN Foundation fund would open. MiMedx denies the remaining allegations in Paragraph 139.

140. When a PAN Foundation fund (either DFU or VLU) opens, reps use the patient information they obtained from reimbursement specialist to submit applications, either online or using the PAN Foundation hotline, for their client's patients.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 140 and, therefore, denies those allegations.

141. Since two of Mr. Vitale's clients—Oconee Medical Center and Upstate Podiatry—would reliably and timely submit in their own patients' application, he simply notified these clinics' staff that the fund was open. However, for all of his other clients, Mr. Vitale personally called in patient applications to the PAN Foundation hotline.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 141 and, therefore, denies those allegations.

142. His colleagues likewise submitted patient applications, some using the Internet and other the telephone hotline.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 142 and, therefore, denies those allegations.

143. In an email sent shortly after the February 2014 announcement, MiMedx management cautioned reps not to alert the company's clients that the fund would be opening or that reps knew when the fund would open.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 143 and, therefore, denies those allegations.

144. Mr. Vitale believes MiMedx executives were concerned that if company customers knew MiMedx reps received advance notice of forthcoming contribution from MiMedx to PAN Foundation funds, customers would alert sales reps for other companies or raises questions as to why patient assistance applications were being held.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 144 and, therefore, denies those allegations.

145. Based on communications from corporate headquarters, MiMedx's executives were aware of the fact that the effect of this scheme was to maximize the number of MiMedx product sales supplemented by PAN Foundation grants. One executive, Roselli bragged about advantage it gave them over their competitors in an open-fund notice to reps:

I am pleased to announce that the PAN VLU fund will be available effective Monday, March 3, 2014.

You all have done a great job identifying VLU patients and submitting IVRs. Now we need to take the next and most important steps first thing Monday!

1. Submit your patients to PAN for approval
2. Start the grafting process
3. GET YOUR POs to MiMedx to prove we are taking full advantage of the PAN fund

Remember this is a first come first serve program and that your competitors like Apilgraf can also submit for funds from PAN.

Move quickly and keep this as our advantage — this is the 20% you need to get patient's covered and grafted

Have a great weekend and be ready to roll on Monday!

See Email from L. Roselli to Sales (attached as **Exhibit E**). By highlighting the fact that PAN Foundation operated on a first-come first-serve basis, Roselli sought to remind reps that MiMedx's scheme would only be successful if the reps submitted applications as soon as the fund opened.

ANSWER: MiMedx admits that Paragraph 145 quotes a portion of the document attached as Exhibit E. MiMedx denies any remaining allegations in Paragraph 145.

146. Notably, two other members of the MiMedx executive team, Vice President of Sales Operations Mark Diaz and Executive Vice President and Chief Commercialization Officer Mike Carlton, received courtesy copies of Roselli's email.

ANSWER: MiMedx admits that Diaz and Carlton are copied on the email that is attached as Exhibit E. MiMedx denies any remaining allegations in Paragraph 146.

147. Similarly, in an October 24, 2016 email sent at 11:16 a.m. to MiMedx sales and reimbursement reps, Director of Reimbursement Colleen DeSantis alerted company reps, "We are anticipating that the PAN DFU fund will open on Monday, October 24th at approximately 12:00 EST. The PAN VLU fund closed this morning. I will send out an email when it is confirmed to be open. Thank you!" Email from C. Desantis to Reimb. Field Mgr. (attached as **Exhibit F**).

ANSWER: MiMedx admits that Paragraph 147 quotes a portion of the document attached as Exhibit F. MiMedx denies any remaining allegations in Paragraph 147.

148. While Mr. Vitale was never privy to the amount in which MiMedx was funding PAN Foundation's DFU and VLU funds, MiMedx's manipulation of PAN Foundation applications and contributions were correlated as part of an intentional scheme to maximize sales by subsidizing copays and coinsurance.

ANSWER: Denied.

149. From approximately April 2014 until the beginning of 2016, regional sales managers contacted reps weekly via email and sometimes text message requesting a report as to the number of PAN Foundation eligible patients that could be rushed into the application pipeline.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 149 and, therefore, denies those allegations.

150. For example, DeFord routinely contacted Mr. Vitale via text message. DeFord was frequently apologetic in his requests claiming he was in a hurry to obtain the information and needed it as soon as possible. He also used email to request these numbers from reps in his region.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 150 and, therefore, denies those allegations.

151. Beginning in sometime in 2016, MiMedx required reps to prepare and submit weekly sales reports tracking sales metrics while also reporting the number of PAN Foundation eligible patients.

ANSWER: Denied.

152. At all times relevant to this complaint, these weekly rep field reports concerning PAN Foundation applicants that could be rushed into the pipeline were “rolled up” to regional sales directors (RSD) who, in turn, created regional reports sent to MiMedx’s regional vice presidents for regions East, Midwest, and West, thus alerting executive management to the exact number of PAN Foundation applicants that would be seeking approval for MiMedx products.

ANSWER: Denied.

153. Moreover, on the several occasions Mr. Vitale forgot to submit patient information to reimbursement specialists prior to the fund opening, but subsequently sought to submit the applications after receiving notice the fund was open, he was unsuccessful in doing so because, according to the PAN Foundation hotline attendant, the fund had already been exhausted even though it had opened just four or five hours earlier.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 153 and, therefore, denies those allegations.

154. In other words, whatever amount MiMedx had recently contributed in order to “open” the fund, that amount failed to account for the patient management was unaware of but that Mr. Vitale subsequently sought to have enrolled, indicating the MiMedx only contributed sufficient funds to cover those patients of which they were already aware.

ANSWER: Denied.

155. When patient applications were accepted, PAN Foundation sent a confirmation letter via fax to the patient’s physician.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 155 and, therefore, denies those allegations.

156. For example, on August 11, 2015, PAN Foundation faxed a letter to Dr. Raymond Corpe, an orthopedic surgeon then at Palmetto Health Advanced Wound Care, concerning his patient, Jane Doe,⁹ informing Dr. Corpe that Ms. Doe would receive a \$3,500 grant reimbursing the cost sharing (i.e., coinsurance) associated with “specific, out-of-pocket *medication* expenses related to Lower Extremity Ulcers.” See Ltr. from PAN Foundation to Dr. Come (emphasis original) (attached as **Exhibit G**). Included in the letter is a Pharmacy Control Number (PCN) for Medicare Part D, indicating Jane Doe is insured through Medicare Part D.

ANSWER: MiMedx admits that Paragraph 156 quotes a portion of the document attached as Exhibit G. MiMedx denies any remaining allegations in Paragraph 156.

157. MiMedx reps received confirmation letters, like the one sent concerning Jane Doe, so they can inform clinic staff of the approval and follow up to schedule the procedure.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 157 and, therefore, denies those allegations.

⁹ Patient information has been redacted to protect the patient’s identity.

158. Mr. Vitale estimates he averaged 25 or more PAN Foundation grants per year over the last three years. This reflected approximately two days of commercial account work each week, where as some of his colleagues likely spend all of their work hours on commercial accounts.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 158 and, therefore, denies those allegations.

159. Companywide, this scheme is believed to have resulted in approximately 7,500 patient assistance grants from PAN Foundation to patients seeking the use of MiMedx product.

ANSWER: MiMedx lacks information sufficient to form a conclusion as to the truth or falsity of the allegations in Paragraph 159 and, therefore, denies those allegations.

MiMedx's Scheme Violates the AKS

160. The AKS prohibits the knowing payment of remuneration to induce a referral.

ANSWER: To the extent Paragraph 160 states legal conclusions, no response is required. MiMedx denies any remaining allegations in Paragraph 160.

161. MiMedx knows it is against the law to pay copays and coinsurance for federally insured patient.

ANSWER: Denied.

162. Instead of making a direct payment to patients or their healthcare provider, MiMedx used the aforementioned scheme to make an *indirect* payment.

ANSWER: Denied.

163. This payment is concealed from patients, healthcare providers, insurers and the government by laundering the funds through PAN Foundation and manipulating the application process to ensure the funds are received by their intended target.

ANSWER: Denied.

164. MiMedx's intent or purpose in paying this remuneration is to ensure federally insured patients receive the company's products and that those products are reimbursed by federal insurance programs. Simply put, this scheme is designed to maximize MiMedx sales at the expense of the federal government and its taxpayers.

ANSWER: Denied.

165. Kickbacks are *malem in se* and compliance with the AKS is a material condition for payment by federal health insurance programs.

ANSWER: To the extent Paragraph 165 states legal conclusions, no response is required.

MiMedx denies any remaining allegations in Paragraph 165.

166. MiMedx's scheme, described above, has caused the submission of false claims.

ANSWER: Denied.

FCA VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(A) & (B)¹⁰

167. Relator re-alleges and incorporates by reference each of the allegations in the preceding paragraphs here.

ANSWER: MiMedx restates and incorporates by reference here each of its responses to the preceding paragraphs.

168. At all times relevant to this action, Defendant was legally obligated to comply with the AKS and other federal laws governing the marketing and sale of drugs and biological products to federally insured patients in the Medicare and FEHBP programs.

ANSWER: To the extent Paragraph 168 states legal conclusions, no response is required.

To the extent the allegations of Paragraph 168 relate to the FEHBP, no further response is

¹⁰ To the extent wrongdoing occurred prior to May 20, 2009, this Complaint also alleges violations of the FCA prior to its recent amendments. See, e.g., 31 U.S.C. § 3729(a)(1) (1986).

required because claims relating to the FEHBP were dismissed. Dkt. 78. To the extent relevant to the issues in this case, the provisions of the AKS and other federal laws governing the marketing and sale of drugs and biological products to federally insured patients in the Medicare program speak for themselves. MiMedx denies any remaining allegations in Paragraph 168.

169. At all times relevant to this action, Defendant was also legally obligated to take corrective action upon discovering it received payment for products provided in derogation of Defendant's obligations under federal law.

ANSWER: To the extent Paragraph 169 states legal conclusions, no response is required. MiMedx denies any remaining allegations in Paragraph 169.

170. Instead, Defendant violated 42 U.S.C. § 1320a-7b by:

- a. Indirectly paying copays and coinsurance to induce federally insured patients to use and seek reimbursement for its products;
- b. Manipulating and coordinating so-called charitable contributions to PAN Foundation with the submission of patient applications seeking use of those funds;
- c. Tracking and holding patient applications for assistance from PAN Foundation to discern whether and when to fund the DFU and VLU funds that eventually receive those applications;
- d. Obtaining and disseminating federally protected patient information in furtherance of its indirect payment of patient copays and coinsurance;
- e. Indirectly paying patient's healthcare providers to recommend or refer the use of MiMedx products;
- f. Incentivizing Defendant's clients and patient's healthcare providers to participate in this scheme by ensuring they would receive reimbursement and profit from for expensive wound care therapies; and
- g. In other such ways as discovered during the litigation of this action.

ANSWER: Denied.

171. Defendant knowingly and willfully violated the AKS with the scheme alleged here.

ANSWER: Denied.

172. Defendant's conduct caused patients and healthcare providers to submit claims for the reimbursement of Defendant's products to federal health insurance programs.

ANSWER: Denied.

173. Defendant's violations of the AKS are material to patients and healthcare providers receiving reimbursement from federal health insurance programs and federal health insurance programs willingness to pay because, had these federal insurance programs known Defendant's conduct, they would have refused to reimburse these claims.

ANSWER: Denied.

174. Defendants violations of the AKS are also material to Defendant's own receipt of payment since because, had it not engaged in the fraudulent conduct alleged here, it would not have benefitted from the sales that are the product of this kickback scheme.

ANSWER: Denied.

175. Defendant knowingly and willfully caused these claims to be presented for payment from federal health insurance programs including Medicare and FEHBP.

ANSWER: Denied.

176. Defendant knew the Medicare and FEHBP programs relied on, and continue to rely on, biological product manufacturers like the Defendant to abide by federal law in marketing and selling their products.

ANSWER: Denied.

177. Defendant has caused and continues to cause the submission of fraudulent claims to federal health insurance programs at great cost to United States taxpayers.

ANSWER: Denied.

178. Defendant's conduct is a violation of 31 U.S.C. § 3729(a)(1)(A) & (B), as amended.

ANSWER: Denied.

* * * * *

MiMedx hereby denies each and every allegation of the Complaint not specifically admitted herein. MiMedx reserves the right to amend as appropriate its answers to the individual paragraphs of the Complaint.

* * * * *

AFFIRMATIVE DEFENSES

First Defense

The Complaint fails to state a claim against MiMedx for which relief can be granted and is barred, in whole or in part, including because MiMedx lacked the required knowledge, MiMedx's conduct did not involve a "false or fraudulent" claim, was not material, was not the cause (proximate or competent cause) of an alleged harm, or did not cause damages.

Second Defense

The Complaint is barred under the FCA pursuant to 31 U.S.C. § 3730(e)(4)(A).

Third Defense

The Complaint is barred under the FCA pursuant to 31 U.S.C. § 3730(b)(5).

Fourth Defense

Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations, borrowing statutes, and/or statutes of repose.

Fifth Defense

Any damages and/or penalties plaintiff seeks above and beyond actual damages, if any, allegedly sustained are in excess of those permitted by law, and violative of the United States Constitution (including the Due Process and Excessive Fines Clauses).

Sixth Defense

Plaintiff's claims are barred, in whole or in part, because the alleged injuries and damages, if any, resulted from an intervening or superceding cause or causes, including, but not limited to, the actions of learned intermediaries such as physicians.

Seventh Defense

Plaintiff's claims are barred, in whole or in part, because acts or omissions of other persons or entities, whether named or unnamed in the Complaint, over whom MiMedx had no supervision or control and for whose actions MiMedx has no legal responsibility, caused or contributed to the alleged damages.

Eighth Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, or laches.

Ninth Defense

Plaintiff's claims challenge actions or speech that are protected by the First Amendment to the U.S. Constitution.

* * * * *

MiMedx reserves the right to amend these defenses and allege further defenses as appropriate and as such defenses become known to it in the course of this action.

WHEREFORE, MiMedx denies any and all liability with regard to plaintiff's claims and prays for judgment as follows:

1. That plaintiff take nothing by way of his Complaint or any of his purported claims for relief;
2. That the Complaint be dismissed with prejudice;
3. That judgment be entered in favor of MiMedx;
4. That MiMedx be awarded its costs of suit incurred in this action, including attorneys' fees; and
5. That MiMedx be awarded such other relief as the Court may deem just and proper.

REQUEST FOR TRIAL BY JURY

MiMedx hereby demands a trial by jury on all claims so triable.

Respectfully submitted,

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June 12, 2019

Charleston, South Carolina